(iv) The name and address of a new primary contact person or resident agent.

(b) No sponsor may relieve itself of responsibilities under the Orphan Drug Act or under this part by assigning rights to another person without:

(1) Assuring that the sponsor or the assignee will carry out such responsibilities; or

(2) Obtaining prior permission from FDA.

[57 FR 62085, Dec. 29, 1992; 58 FR 6167, Jan. 26, 1993]

§ 316.28 Publication of orphan-drug designations.

Each month FDA will update a publicly available cumulative posting of all drugs designated as orphan drugs. These postings will contain the following information:

(a) The name and address of the sponsor;

(b) The generic name and trade name, if any, or, if neither is available, the chemical name or a meaningful descriptive name of the drug;

(c) The date of the granting of orphan-drug designation;

(d) The designated use in the rare disease or condition; and

(e) If the drug loses designation after August 12, 2013, the date of it no longer having designation.

[78 FR 35134, June 12, 2013]

§ 316.29 Revocation of orphan-drug designation.

(a) FDA may revoke orphan-drug designation for any drug if the agency finds that:

(1) The request for designation contained an untrue statement of material fact; or

(2) The request for designation omitted material information required by this part; or

(3) FDA subsequently finds that the drug in fact had not been eligible for orphan-drug designation at the time of submission of the request therefor.

(b) For an approved drug, revocation of orphan-drug designation also suspends or withdraws the sponsor's exclusive marketing rights for the drug but not the approval of the drug's marketing application.

(c) Where a drug has been designated as an orphan drug because the prevalence of a disease or condition (or, in the case of vaccines, diagnostic drugs, or preventive drugs, the target population) is under 200,000 in the United States at the time of designation, its designation will not be revoked on the ground that the prevalence of the disease or condition (or the target population) becomes more than 200,000 persons.

(d) If FDA revokes orphan-drug designation, FDA will publicize that the drug is no longer designated in accordance with § 316.28(e).

[57 FR 62085, Dec. 29, 1992, as amended at 78 FR 35134, June 12, 2013]

§ 316.30 Annual reports of holder of orphan-drug designation.

Within 14 months after the date on which a drug was designated as an orphan drug and annually thereafter until marketing approval, the sponsor of a designated drug shall submit a brief progress report to the FDA Office of Orphan Products Development on the drug that includes:

(a) A short account of the progress of drug development including a review of preclinical and clinical studies initiated, ongoing, and completed and a short summary of the status or results of such studies.

(b) A description of the investigational plan for the coming year, as well as any anticipated difficulties in development, testing, and marketing; and

(c) A brief discussion of any changes that may affect the orphan-drug status of the product. For example, for products nearing the end of the approval process, sponsors should discuss any disparity between the probable marketing indication and the designated indication as related to the need for an amendment to the orphan-drug designation pursuant to § 316.26.

Subpart D—Orphan-drug Exclusive Approval

§ 316.31 Scope of orphan-drug exclusive approval.

(a) FDA may approve a sponsor's marketing application for a designated orphan drug for use in the rare disease or condition for which the drug was